

NIHR Performance Metrics - Initiating Clinical Research

Quarter 3 (2014-2015)

Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Benchmark Met	Reasons for delay
13/LO/0291	Insight Insulin Pump EU Study: A European Multicenter Study to Evaluate the Accu-Chek® Insight Insulin Pump in Routine Practice	09/12/2013	18/08/2014	NO	Contracting delays and Staff availability
11/YH/0290	STOMP: Small cell lung cancer Trial of Olaparib (AZD2281) as Maintenance Programme: a randomised, double blind, multicentre phase II trial	14/01/2014	None	NO	Strict Eligibility
13/SC/0515	Validity study for the 'Dejour Test', a non-invasive way of measuring oxygen sensitivity from an exhaled breath test, & its use in chronic type II respiratory failure	13/09/2013	28/01/2014	NO	Sponsor delays in submission documentation
13/SC/0490	A PHASE III, Randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of lebrikizumab in adolescent patients with severe uncontrolled asthma who are on inhaled corticosteroids and a second controller medication (WB28183)	19/11/2013	25/11/2014	NO	Site Initiation Delay & Staff Availability
13/NW/0612	A multicentre, randomised, doubleblind, parallel group, placebocontrolled, phase III efficacy and safety study of benralizumab (MEDI-563) added to highdose inhaled corticosteroid plus longacting B2agonist in patients with uncontrolled asthma (SIROCCO)	03/02/2014	21/05/2014	NO	Pharmacy Greenlight & Sponsor delay
13/LO/1245	A Phase 1b, Multicenter, Pilot, Randomized, Double-blind Trial to Determine the Pharmacokinetics and Pharmacodynamics of Orally Administered Tolvaptan 3.75, 7.5, and 15 mg Tablets in Subjects with Syndrome of Inappropriate Antidiuretic Hormone Secretion (Otsuka 156-12-203)	26/02/2014	23/04/2014	YES	

13/NW/0698	A phase III multicenter, randomized study of oral LDK378 versus standard chemotherapy in previously untreated adult patients with ALK rearranged (ALK positive), stage IIIB or IV, non squamous nonsmall cell lung cancer (CLDK378A2301) patients with ALK rearranged (ALK positive), stage IIIB or IV, non squamous nonsmall cell lung cancer (CLDK378A2301)	19/02/2014	01/08/2014	NO	Rare Disease
13/YH/0282	Openlabel, Phase IIIb study to evaluate the efficacy and safety of subcutaneous (SC) Tocilizumab monotherapy or combination therapy with methotrexate (MTX) or other nonbiologic disease modifying antirheumatic drugs (DMARDs) in patients with severe Rheumatoid Arthritis (RA) who are being treated with an antitumournecrosis factor (antiTNF) agent and that have not achieved an adequate response to treatment	14/03/2014	22/05/2014	YES	
13/LO/1795	A double-blind, randomized, placebo-controlled, cross-over study to evaluate the clinical efficacy and safety of subcutaneous administration of human plasma-derived C1-esterase inhibitor in the prophylactic treatment of hereditary angioedema (CSL830_3001)	18/03/2014	CLOSED	NO	Study closed to non-recruiting sites
13/YH/0389	A 52 week, phase 3 double-blind, randomized, placebocontrolled, parallel-group study to assess the efficacy, safety and tolerability of pf-04950615 in subjects with heterozygous familial hypercholesterolemia (B1481021)	24/03/2014	03/06/2014	NO	Strict Eligibility
13/NW/0829	A 52 week, double-blind, randomized, multinational, multi-centre, 2 arm parallel group, active controlled clinical trial of fixed combination of beclometasone dipropionate plus formoterol fumarate plus glycopyrrolate bromide administered via pMDI (CHF 5993) versus fixed combination of beclometasone dipropionate plus formoterol fumarate administered via pMDI in Patients with Chronic Obstructive Pulmonary Disease	18/03/2014	12/05/2014	YES	
12/LO/1078	A phase II randomised trial of carfilzomib, cyclophosphamide and dexamethasone (CCD) vs cyclophosphamide, velcade and dexamethasone (CVD) for first relapse or primary refractory multiple myeloma	03/04/2014	24/07/2014	NO	Pharmacy Greenlight & Site Initiation Delay
14/WM/0027	A Multinational, Randomised, DoubleBlind,Placebo Controlled Trial to Evaluate the Effect of Ticagrelor 90 mg twice daily on the Incidence of Cardiovascular Death, Myocardial Infarction or Stroke in Patients with Type 2 Diabetes Mellitus (THEMIS) daily on the Incidence of Cardiovascular Death, Myocardial Infarction or Stroke in Patients with Type 2 Diabetes Mellitus (THEMIS)	01/04/2014	CLOSED	NO	Study closed to non-recruiting sites
11/EM/0310	The effect of intravenous iron on postoperative transfusion requirements in hip fracture patients – a pilot study	07/04/2014	None	NO	Strict Eligibility

12/NW/0361	A pragmatic randomised controlled trial comparing the effectiveness and cost effectiveness of levetiracetam and zonisamide versus standard treatments for epilepsy: a comparison of Standard And New Antiepileptic Drugs (SANAD-II)	15/04/2014	01/07/2014	NO	Site activation delay
13/WA/0084	A Randomised, DoubleBlind, PlaceboControlled, Multicenter Study to Assess Cardiovascular Outcomes Following Treatment with MK3102 in Subjects with Type 2 Diabetes Mellitus	04/04/2014	15/07/2014	NO	Site Initiation Delay & Pharmacy Greenlight
13/LO/0145	A multicentre phase III randomised controlled single masked clinical trial to test the clinical efficacy of LightMasks at preventing dark adaptation in the treatment of early diabetic macular oedema	29/04/2014	19/09/2014	NO	NHS Permission delayed
14/SC/0104	A Phase 2b, Randomized, Double blind, Placebocontrolled, Parallel group, Multicentre, Dose finding Study to evaluate the Efficiency, Safety and Tolerability of AZD11722 to Treat Hyperphosphataemia in EndStage Renal Disease on Haemodialysis(ESRDHD)	08/04/2014	08/07/2014	NO	Site activation delay
12/WM/0335	OCS-Care: A pilot study for developing and evaluating a core pathway for cognitive problems after stroke	13/05/2014	25/07/2014	NO	Sponsor delay
13/SC/043	Adjuvant steroids in adults with pandemic influenza (ASAP)	14/05/2014	None	NO	Pandemic Study
14/WM/0057	Multi-centre randomised controlled trial to compare the clinical and cost-effectiveness of a 'vein bypass first' with a 'best endovascular first' revascularisation strategy for severe limb ischaemia due to infra-popliteal arterial disease: Bypass vs. Angioplasty in Severe Ischaemia of the Leg. The BASIL-2 trial	14/05/2014	22/07/2014	YES	
08/H0305/38	Evaluation of a tailored text message intervention for pregnant smokers (MiQuit): A proof of concept trial.	20/05/2014	11/06/2014	YES	
14/SC/0065	A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of Canagliflozin on Renal Endpoints in Adult Subjects With Type 2 Diabetes Mellitus	19/05/2014	03/09/2014	NO	Strict Eligibility

13/EM/0349	MANTA - A Phase II, randomized, placebo-controlled study of Fulvestrant in combination with the dual mTOR inhibitor AZD2014 or Everolimus or Fulvestrant alone in ER-positive metastatic breast cancer	21/05/2014	30/07/2014	YES	
14/EE/0032	Treating dry eyes and corneal ulcers with fingerprick autologous blood	03/06/2014	29/10/2014	NO	Unpredicable Patient Population
14/SC/0092	A multi-centre randomised, double blind, placebo-controlled, parallel group trial of the effectiveness of the nocturnal use of a Temperature Controlled Laminar Airflow (TLA) Device (Airsonett®) in adults with poorly controlled, severe allergic asthma	11/06/2014	15/08/2014	YES	
14/EM/0186	A Randomized Controlled Phase 3 Study of Oral Pacritinib versus Best Available Therapy in Patients with Thrombocytopenia and Primary Myelofibrosis, Post Polycythemia Vera Myelofibrosis, or PostEssential Thrombocythemia Myelofibrosis	30/06/2014	18/12/2014	NO	Strict Eligibility
13/NI/0072	A Phase 4, Open-label, Single-Arm Study of Brentuximab Vedotin in Patients With Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma	25/06/2014	None	NO	Rare Disease
14/NW/0130	A randomised, double blind, multi-center, placebo-controlled study to evaluate the efficacy, safety, and tolerability of NT100 in pregnant women with a history of unexplained recurrent pregnancy loss (RPL)	17/07/2014	19/08/2014	YES	
14/LO/0717	A Multicenter Phase 3 Randomized Open-Label Study of Bosutinib versus Imatinib in Adult Patients with Newly Diagnosed Chronic Phase Chronic Myelogenous Leukaemia	04/08/2014	None	NO	Rare Disease
09/H1005/28	Molecular genetics of adverse drug reactions: from candidate genes to genome wide association studies.	19/08/2014	22/10/2014	YES	
14/YH/0085	Front-Line therapy in CLL: Assessment of Ibrutinib + Rituximab (A Phase III trial to assess ibrutinib + R against FCR in previously untreated patients with Chronic Lymphocytic Leukaemia (CLL)	26/08/2014	01/10/2014	YES	

13/ES/0005	A phase 3, multi centre, randomized, double blind study to compare the efficacy and safety of oral azacitidine plus best supportive care versus placebo plus best supportive care in subjects with red blood cell transfusion dependent anaemia and thrombocytopenia due to ipss lower-risk myelodysplastic syndromes	15/09/2014	16/12/2014	NO	Strict Eligibility
11/H1016/3	Understanding haemodialysis vascular access maturation: A prospective observational study to understand natural history and biology of AV access maturation and identify risk factors for AVF failure.	26/09/2014	27/11/2014	YES	
13/LO/0108	A randomised phase II study comparing LEnalidomide plus rituximab, GEmcitabine and methylprednisolone (LR-GEM) to rituximab, gemcitabine, methylprednisolone and cisplatin (RGEM-P) in secondline treatment of Diffuse Large Bcell lymphoma (DLBCL)	29/09/2014	None	NO	Strict Eligibility
13/EM/0395	Treatment of Advanced Glaucoma Study (TAGS): A multicentre randomised controlled trial comparing primary medical treatment with primary augmented trabeculectomy for people with newly diagnosed advanced glaucoma	07/10/2014	25/11/2014	YES	
12/WA/0185	Goal-oriented cognitive rehabilitation in early stage dementia: multi-centre single-blind randomised controlled trial (GREAT)	02/10/2014	10/12/2014	YES	
13/LO/0699	Evaluating the effects of the novel GLP1 analogue, liraglutide, in patients with Alzheimer's disease (ELAD study)	21/10/2014	29/12/2014	YES	
13/NW/0265	A trial of de-escalation and stopping treatment in chronic myeloid leukaemia patients with excellent responses to tyrosine kinase inhibitor therapy	24/10/2014	23/12/2014	YES	
11/EM/0393	A randomised phase IIa study (with combination safety run-in) to assess the safety and efficacy of AZD4547 in combination with either anastrozole or letrozole versus exemestane alone in ER positive breast cancer patients who are progressing on current treatment with anastrozole or letrozole	24/10/2014		Within	
14/NE/0011	A randomised controlled trial of sildenafil therapy in severe, early onset intrauterine growth restriction: STRIDER trial	29/10/2014		Within	

11/WM/0235	Outcomes of Periodontal Therapy in Rheumatoid Arthritis	04/11/2014	13/11/2014	YES	
13/LO/1517	A Phase 3, Randomized, Open-Label, Active-Controlled Study to Evaluate the Efficacy and Safety of FG-4592 in the Treatment of Anemia in Chronic Kidney Disease Patients Not on Dialysis of Anemia in Chronic Kidney Disease Patients Not on Dialysis	04/11/2014	17/12/2014	YES	
14/EE/0204	What is the clinical effectiveness of hydrotherapy in maintaining physical function in people with Duchenne muscular dystrophy?	05/11/2014	23/12/2014	YES	
14/NE/1143	The feasibility of undertaking Appendicectomy to impact upon the Clinical Course of Ulcerative Colitis The ACCURE Trial Feasibility Study	28/11/2014		Within	
14/WM/0170	A Phase 3, Randomized Study to Evaluate the Efficacy of Momelotinib versus Best Available Therapy in Anemic or Thrombocytopenic Subjects with Primary Myelofibrosis, Post-polycythemia Vera Myelofibrosis, or Post-essential Thrombocythemia Myelofibrosis who were Treated with Ruxolitinib.	21/11/2014		Within	
14/WS/1014	Wave IV Study: Phase II Randomized Sham Controlled Study of Renal Denervation for Subjects with Uncontrolled Hypertension	03/12/2014	08/12/2014	YES	
13/WA/0205	A Trial for Older Patients with Acute Myeloid Leukaemia and High Risk Myelodysplastic Syndrome	04/12/2014		Within	
13/SC/0638	Human papillomavirus infection: a randomised controlled trial of Imiquimod cream (5%) versus Podophyllotoxin cream (0.15%), in combination with quadrivalent human papillomavirus or control vaccination in the treatment and prevention of recurrence of anogenital warts (HIPvac Trial)	03/12/2014		Within	
12/WM/0340	Locking plate fixation versus intramedullary nail fixation for patients with a displaced, extraarticular fracture of the distal tibia: a randomised trial and economic evaluation.	16/12/2014		Within	

11/NW/0246	STAR: A randomised multi-stage phase II/III trial of Standard first line therapy (sunitinib or pazopanib) comparing Temporary cessation with Allowing continuation, in the treatment of locally advanced and/or metastatic Renal cancer	19/12/2014		Within	
10/H0302/51	TB Reach - Sub-study 5: Improving the management and control of tuberculosis among hard to reach groups	22/12/2014		Within	
14/LO/1842	ENDCaP-C Test Accuracy Study	12/12/2014		Within	